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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,083	04/19/2004	Yao Xiong Hu	3352.2.1.4	2771

7590 04/28/2005  
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EXAMINER

SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/827,083	<b>Applicant(s)</b> HU, YAO XIONG	
	<b>Examiner</b> A R. Salimi	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/26/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Claims 1-20 are pending.

Raw Sequence Listing has been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

#### *Priority*

The reference to parent application(s) is acknowledged. However, the current status of the parent application should also be present. Please up-date the priority information by inserting the patent number.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dillner et al (US Patent No. 5,932,412), and Schoolnik et al (US Patent No. 4,777,239).

Dillner et al taught method of screening for human papillomavirus type 16 (HPV-16) employing the E7 protein in general, and in particular the portion of E7 identified as SEQ ID NO: 53 (see Claim 1-8), which comprises the same polypeptide as now claimed by the Applicants designated as SEQ ID NO: 4. Dillner et al identified small regions within the various ORFs of HPV-16 to be utilized in a diagnostic assay (see Column 2, lines 19-29). In

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addition, Dillner et al taught various well known detection methods (see Column 6, lines 34-67, and Column 7, lines 1-67). This only differs since they did not add cysteine linkers.

Schoolnik et al taught the use of human papillomavirus (HPV) peptide in a diagnostic assay (see column 4, lines 53-57, and column 9, lines 59-68), tissue type, and the virus type i.e. HPV-16 (see column 10, lines 14-18), including the various regions that could be utilized such as E7 protein (see claim 1). Still further the above cited patent taught addition of one or more cysteine residues (see column 5, lines 17-25). Schoolnik et al also provided teaching for several well known assays in detecting papillomavirus infection (see Column 12, lines 41-66).

Therefore, one of ordinary skill in the art at the time of filing would have been highly motivated by the above cited art to use the polypeptide taught by Dillner et al in detection of papillomavirus. Dillner et al taught the SEQ ID NO: 53 a short polypeptide, which comprises the SEQ ID NO: 4, and the claimed invention only differs because of absence of a well known linker. However, using a linker is also well known to those ordinary skill in the art as a technique for purification or stabilizing the protein to better avail their antigens in detection assays, as taught by Schoolnik et al. The above cited patents provided the protein, and the region that is important for determining the presence and exposure to the papillomavirus. In addition, Schoolnik et al provided teaching for addition of cysteine linkers, and as to why addition of linker would be helpful. Thus, one of ordinary skill in the art would have had ample motivation to use the linker taught by Schoolnik et al and add it to the Dillner's et al polypeptide to detect antibodies in tissues that may contain human papillomavirus type 16, or exposure to virus as

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such. One of ordinary skill in the art being familiar with the above cited art would not have anticipated any unexpected results, and the specification does not provide any. The cited art taught the peptide as well as a method of detecting. The series of recited methods in the claims belong to familiar host of routine detection techniques. Certain limitations that may not be present in the above cited art are considered to be a design choice, unless their proof of criticality is/are proven. Hence, the invention as a whole is considered prima facie obvious absent any unexpected results.

No claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

4/27/2005

ALI R. SALIMI  
PRIMARY EXAMINER